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The Mentholatum Co., Inc.

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www.mentholatum.com

Submitted by Fax

October 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: October 14, 2003 Comments to Docket No. 78N-0301; External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

Dear Sir or Madam:

We wish to assure FDA that The Mentholatum Company does not claim any privilege for anything in the material submitted on October 14, 2003. This information is considered part of the public docket.

Sincerely,

Joyce L. Miller

Joyce L. Miller
Director, Regulatory Affairs

The Mentholatum Co., Inc.

707 Sterling Drive
Orchard Park, NY 14127-1587
716-677-2500 • 800-688-7660
Fax: 716-675-2783

FAX TRANSMITTAL

DATE: October 28, 2003

TO: Latroy Tinch
Dockets Management Branch
Food and Drug Administration
301-827-6868

FAX: 301-827-6870

FROM: Joyce L. Miller
Director, Regulatory Affairs
Ext. 1572

TOTAL PAGES: 2

In response to your telephone contact, please see attached letter regarding The Mentholatum Company's comments to Docket No. 78N-0301 on October 14, 2003.

IAPR

INSTITUTE FOR APPLIED PHARMACEUTICAL RESEARCH, LTD. 214 SYCAMORE AVENUE, MERION, PA 19066

January 17, 1996

Henry H. Chan, Ph.D.
Director of Product Development
The Mentholatum Company, Inc.
1360 Niagara Street
Buffalo, NY 14213

Re: Project #6907

Dear Henry,

Enclosed are two copies of the protocol for the screening of reformulated Pain Patch #157 for safety under exaggerated use conditions. Application of patches will be made 3 times daily for 14 days, followed by a 10-day rest period.

This modified irritation/sensitization study combines the usual safety methods with an exaggerated in-use test.

Please sign the two copies as confirmation of your acceptance of the protocol and return one copy for our files.

We shall initiate this study in mid-January, 1996.

Sincerely,

Elias W. Packman, Sc.D.

Enclosures

EWP/mg

Project 6907

MODIFIED IRRITATION - SENSITIZATION SCREENING UNDER EXAGGERATED USE CONDITIONS PAIN PATCH #157

Protocol

Consent Form

IRB Approval Letter

PROTOCOL

SPONSOR: The Mentholatum Company, Inc.

INVESTIGATORS: Elias W. Packman, Sc.D.
Barry Packman, M.D.
Institute for Applied Pharmaceutical Research, Ltd.

TITLE: Modified Irritation - Sensitization Screening
Under Exaggerated Use Conditions
Pain Patch #157

THE MENTHOLATUM COMPANY, INC.

Protocol

MODIFIED IRRITATION - SENSITIZATION SCREENING STUDY UNDER EXAGGERATED USE CONDITIONS

Pain Patch 157

Project Name:

Fourteen-Day In-Use Irritation/Sensitization Screening Study.

Objective:

To evaluate the safety of a reformulated Pain Patch containing a water soluble adhesive under exaggerated use conditions.

Sample to be Tested:

One entire Pain Patch #157 (4" x 5-12") as marketed.

Subjects Inclusion:

Twenty-five (25) adult volunteers between 18 and 65 years of age will be recruited for this investigation.

A. Inclusion Criteria

1. Individuals 18 years of age or older.

2. Individuals free of any systemic or dermatologic disorder which, in the opinion of the investigative personnel, would interfere with the study results.

3. Individuals with uniformly-colored skin on the lower thoracic area of the back which would allow a discernible erythema.

4. Individuals who complete a patch evaluation Medical Screening form as well as a Medical/Personal history form.

B. Exclusion Criteria

1. Individuals with any visible skin disease at the study site, which in the opinion of the investigative personnel, would interfere with the evaluation.

2. Individuals receiving systemic or topical drugs or medication which, in the opinion of the investigative personnel, would interfere with the study results.

3. Individuals who are being treated for asthma.

4. Individuals with psoriasis and/or active topic dermatitis/eczema.

5. Females who are pregnant, planning a pregnancy, or nursing a child.

6. Individuals with a known sensitivity to cosmetics, skin care products, or topical drugs as related to product(s) being evaluated.

Methodology

Each volunteer will report to the study site at 7 a.m., 1p.m., and 7 p.m. each day. At each time, a patch will be applied to the upper non-dominant arm. As the old patch is removed and before the new patch is applied, the area under the patch will be observed. Patches will be applied three times daily for 14 days (42 patches), then there will be a 10-day rest period followed by a challenge patch. The challenge patch will be applied to the upper dominant arm.

Observations:

The skin which had been covered by the patch will be examined and scored for irritation as each patch is removed (1 p.m., 7 p.m., and 7 a.m.). After the 14 days of patch application and observation/scoring, there will be a 10-day rest period followed by a challenge patch. After 6 hours, the challenge patch will be removed, and observations and scoring made 24 and 48 hours after removal.

Scoring

Scoring of the area under the patch will be based on a 6-point scale as follows:

IRRITATION - SENSITIZATION STUDY

SCORING SCALE

/ 0 = No Reaction
± = Questionable Erythema
+1 = Definite Erythema
+2 = Erythema & Edema
+3 = Erythema, Edema & Vesiculation
+4 = Erythema, Edema, Vesiculation, Hemorrhage & Bulla Formation

Challenge Observations

Challenge patch will be applied after the 10-day rest period. After 6 hours, the patch will be removed and observations made immediately upon removal and 24, and 48 hours after patch removal.

Documentation of Data

The case report forms will be designed to identify each subject by subject number and/or subject entry number and, where appropriate, subject's initials, the product(s) evaluated, and the reactions observed. Originals or copies of all case report forms, source documents, IRB documents, if required, correspondence, study reports, etc., will be kept on hard-copy file at IAPR for a minimum of three (3) years from completion of the study. They are available for the Sponsor's review on the premises of IAPR.

Adverse Reactions

Any unusual or serious reaction, or any unusual frequency of reactions will be reported by telephone to the Sponsor. It is understood that the investigator will stop application of the study material at any time that he feels the subject's condition so indicates.

Monitoring of the Study

The Sponsor make site visits during the course of the study and may inspect all case report forms and all other documentation directly associated with the study.

Final Report

At the conclusion of the study, the Sponsor will receive a complete report including a general summary (abstract), a detailed description of objective, rationale, background data, study materials, experimental design, procedures, tables of raw data and data summary, and an interpretation with discussion of results.

Institutional Review

The protocol and all addenda for this study will be reviewed by an appropriate Institutional Review Board, if required. A Letter of Approval will be kept on file.

Informed Consent:

A properly-executed informed consent document in compliance with FDA regulations will be obtained from each subject prior to entering the study. The signed informed consent is maintained in the study file. In addition, the subject will be provided with a copy of the informed consent.

Investigator's Agreement:

IAPR agrees to conduct the title study as provided in this protocol, in accordance with all government regulations and to make no changes without prior notification to the Sponsor except where a modification is deemed necessary to eliminate or reduce risk to human subjects.

ACCEPTED:

The Mentholatum Company, Inc.

Jan 19, 1996
Date

The Institute for Applied Pharmaceutical Research, Ltd.

1/17/96
Date

IAPR

Project 6907

Subject #_____

CONSENT TO PARTICIPATE IN IRRITATION-SENSITIZATION STUDY

PROJECT TITLE
Modified Irritation - Sensitization Screening Under Exaggerated Use Conditions Pain Patch #157

TEST MATERIALS
Reformulated Patch #157 as marketed (4" x 5-1/2")

DOSING/APPLICATION
One (1) patch three times each day (6 hours apart) for fourteen (14) days, with a challenge ten (10) days later.

PROCEDURE
Three (3) reformulated Pain Patches will be applied to the non-dominant upper arm each day for fourteen (14) days. Observations will be made as the old patch is removed and a new one applied. After a ten (10) day rest period, a patch will be applied for six (6) hours then removed and observations made immediately and after 24 and 48 hours. Twenty-five (25) subjects will participate. Observations/scoring will be made twice daily when the patches are removed and each morning when a new patch is applied.

SUBJECTS
Twenty-five (25) healthy male and female volunteers 18 years of age and older, who are free of skin disease and have no history of allergy will be enrolled for this test.

PREGNANCY (FEMALES ONLY)
To the best of my knowledge, I am not currently pregnant and I aver that I practice acceptable birth control procedures.

GENERAL HEALTH
I am in generally good health, have no history of allergies, and am free of skin disease. To the best of my knowledge, I have no sensitivities to substances, including medications which are applied to the skin.

COMPENSATION
In consideration of the remuneration to be paid to me, I agree that I will follow all instructions faithfully to the best of my ability, and allow the Investigator to proceed with the test. I have also been assured that I am free to discontinue participation at any time because of adverse reactions or any other reason without prejudice. I am aware that, if I fail to complete the study requirements for other than medical or other valid reasons, I will be paid proportionately for my participation.

BENEFITS/RISKS
In the concentrations applied, no unusual side effects are expected. However, in the sensitive individual, symptoms of itching, redness, and in severe cases swelling and burning may occur, although this is unlikely. The benefit for subjects is the remuneration which is received for participation.

(Please turn over)

PROTECTION OF PARTICIPANT

It is unlikely that I will suffer any physical injury as a result of participating in this experiment; however, if I should, the Sponsor will pay the reasonable cost for the appropriate medical treatment of any injury directly attributable to my participation in this study. Treatment will not be provided, however, for pre-existing injuries not attributable to study participation.

AVAILABLE INFORMATION

I understand that I am free to contact Dr. Elias Packman at (610) 623-2100, or the chairperson of the IRB, Ms. Beverly Hayden at (215) 596-8894, at any time with any additional questions I might have concerning the experimental procedures or attendant risks.

RIGHT TO WITHDRAW/CONFIDENTIALITY

I am free to discontinue participation at any time without prejudice. Your doctor may withdraw you from the study at any time he/she feels it is in your best interest. Any information obtained in connection with this project which can be identified with me will remain confidential and will be disclosed only with my permission. However, the authorized sponsor of this study, The Mentholatum Company, and the Food and Drug Administration and/or other governmental agencies may review records pertaining to this study. I will not be identified by name in any published report. My signature indicates that I have read this consent form, and that all the details of my participation as a subject have been explained to me to my satisfaction. My participation in this study is voluntary.

Signature_____ Date_____

Witness_____ Date_____

Social Security #_____

PLEASE PRINT:

Name_____

Address_____

Phone_____ Age_____ Sex_____ Birth Date_____

Occupation_____

IAPR

INSTITUTIONAL REVIEW BOARD

January 23, 1996

Dr. E. W. Packman
Director
Institute for Applied Pharmaceutical Research, Ltd.

Dear Dr. Packman:

I am pleased to inform you that the Human Research Review Committee for IAPR reviewed and approved the consent form and the human safety aspects of the proposed study entitled:

> "Fourteen-Day In-Use Irritation - Sensitization Screening Study under Exaggerated Use Conditions", sponsored by The Mentholatum Company, Inc., IAPR Project 6907,

at its conference on January 22, 1996.

Sincerely,

Beverly S. Hayden,
Committee Chairman

It is understood that it is the investigator's responsibility to notify the Committee immediately of any untoward results of this study to permit review of the matter. In such case, the investigator should call Ms. Beverly S. Hayden at 215-596-8894.

INSTITUTE FOR APPLIED PHARMACEUTICAL RESEARCH, LTD. 214 SYCAMORE AVENUE, MERION, PA 19066

February 26, 1996

Henry H. Chan, Ph.D.
Director of Product Development
The Mentholatum Company, Inc.
1360 Niagara Street
Buffalo, NY 14213

Re: Project #6907

Dear Dr. Chan:

We have completed the Modified Irritation-Senitization Screening Under Exaggerated Use Conditions of Pain Patch #157, our Project #6907.

The study was conducted according to the protocol of January 17, 1996. Twenty-five volunteers were patched 3 times daily and observed prior to the application of each patch. After 14 days, the subjects were given a 10-day rest period and then challenged with a single Pain Patch #157 for 6 hours and observations made 24 and 48 hours later.

The data clearly suggests that there is minimal potential for acute skin irritation under the conditions of use employed in this investigation. The erythema which was noted during the acute phase of the screening dissipated within 4 hours of the removal of the last patch. The results reflect the conclusion that Pain Patch #157 has a low order of potential for inducing acute irritation with repeated use.

After the 10-day rest period and the challenge patch applied, there was no evidence of any irritation at 24 or 48 hours, suggesting that no sensitization had occurred. These results reinforce the conclusion that under the conditions of this test, Patch #157 has little or no potential as a sensitizing product.

Sincerely,

Elias W. Packman, Sc.D.

Enclosures

EWP/mg

Project 6907

MODIFIED IRRITATION - SENSITIZATION SCREENING

UNDER EXAGGERATED USE CONDITIONS

PAIN PATCH #157

Results

SUMMARY OBSERVATIONS - PATCH #157

Modified Irritation/Sensitization

	SCORES				
	±	+1	+2	+3	+4
Days	Observations/Total Subjects				
1	0/25	1/25	0/25	0/25	0/25
2	4/25	3/25	0/25	0/25	0/25
3	1/25	1/25	0/25	0/25	0/25
4	1/25	1/25	0/25	0/25	0/25
5	1/25	1/25	0/25	0/25	0/25
6	2/25	2/25	0/25	0/25	0/25
7	2/25	1/25	0/25	0/25	0/25
8	0/25	1/25	0/25	0/25	0/25
9	0/25	1/25	0/25	0/25	0/25
10	0/25	1/25	0/25	0/25	0/25
11	0/25	1/25	0/25	0/25	0/25
12	0/25	1/25	0/25	0/25	0/25
13	1/25	1/25	0/25	0/25	0/25
14	0/25	1/25	0/25	0/25	0/25

POST CHALLENGE

	SCORES				
	±	+1	+2	+3	+4
	Observations/Total Subjects				
24 Hours	0/25	0/25	0/25	0/25	0/25
48 Hours	0/25	0/25	0/25	0/25	0/25

Discussion and Conclusion

Under the conditions of this Modified Irritation-Sensitization Screening Under Exaggerated Use Conditions, the potential for acute irritation with repeated cases of Pain Patch #157 is minimal. One volunteer reacted with definite erythema after each patch was removed, but at the conclusion of the 14-day insult period, the redness proved transient and was dissipated within four hours.

The absence of reaction after a challenge patch was applied following a 10-day rest period is highly suggestive that sensitization is not a consideration with repeated use of Pain Patch #157.

These screening results suggest that Pain Patch #157 has a low order of potential for inducing acute irritation with repeated use and little or no potential for sensitization with repeated use.

OBSERVATION OF SENSITIZATION

Following a 10-day rest period, the volunteers were patched with 1 Pain Patch #157 for 6 hours. Observations were made 24 and 48 hours after patch removal.

24 Hours Post Challenge

No Reaction

48 Hours Post Challenge

No Reaction

No evidence of sensitization was observed with Pain Patch #157.

ADDENDUM

Two volunteers exhibited a surface hematoma as a result of traumatic removal of the patches on day 2*. These subjects were dropped from the study but observed daily. The discoloration slowly regressed and was completely gone in 8-10 days in both of the subjects.

They were replaced in the study by the alternates who had started the irritation/sensitization screening study at the same time.

* A total of 6 patches had been applied.

Project 6907

MODIFIED IRRITATION - SENSITIZATION SCREENING

UNDER EXAGGERATED USE CONDITIONS

PAIN PATCH #157

Raw Data

IRRITATION - SENSITIZATION STUDY

Project 6907

Pain Patch 157

APPLICATIONS

	SUB. I.D.	DATES 11/25/96	11/26/96	11/27/96	11/28/96	11/29/96
1	P.R	3	3	3	3	3
2	G.M	3	3	3	3	3
3	M.R	3	3	3	3	3
4	A.N.	3	3	3	3	3
5	K.S.	3	3	3	3	3
6	J.T	3	3	3	3	3
7	M.M.C	3	3	3	3	3
8	D.C	3	3	3	3	3
9	J.N	3	3	3	3	3
10	E.D	3	3	3	3	3
11	D.T	3	3	3	3	3
12	G.H	3	3	3	3	3
13	.K	3	3	3	3	3
14	J.R	3	3	3	3	3
15	J.N.T	3	3	3	3	3
16	J.D	3	3	3	3	3
17	A.V	3	3	3	3	3
18	T.D	3	3	3	3	3
19	J.T	3	3	3	3	3
20	G.T	3	3	3	3	3
21	R.K.	3	3	3	3	3
22	D.L	3	3	3	3	3
23	M.P	3	3	3	3	3
24	C.M	3	3	3	3	3
25	J.R	3	3	3	3	3

Technician

Investigator

11/29/96
Date

IRRITATION - SENSITIZATION STUDY

Project 690

Pain Patch 157

APPLICATIONS

SUB. I.D.	DATES 1-30-96	1-31-96	2-1-96	2-2-96	2-3-96
1-PR	3	3	3	3	3
2-GM	3	3	3	3	3
3-MR	3	3	3	3	3
4-AN	3	3	3	3	3
5-KS	3	3	3	3	3
6 QT	3	3	3	3	3
7 MMc	3	3	3	3	3
8 LBC	3	3	3	3	3
9 GN	3	3	3	3	3
10 TD	3	3	3	3	3
11 DT	3	3	3	3	3
12 GH	3	3	3	3	3
PR	3	3	3	3	3
14 QR	3	3	3	3	3
15 MT	3	3	3	3	3
16 QD	3	3	3	3	3
17 AV	3	3	3	3	3
18 TD	3	3	3	3	3
19 QT	3	3	3	3	3
20 AT	3	3	3	3	3
21 RR	3	3	3	3	3
22 SL	3	3	3	3	3
23 MP	3	3	3	3	3
24 MM	3	3	3	3	3
25 PJR	3	3	3	3	3

Technician

Investigator

2/3/96
Date

HAPR

IRRITATION - SENSITIZATION STUDY

Project 690

Pain Patch 157

A P P L I C A T I O N S

	DATES				
SUB. I.D.	2-4-96	2-5-96	2-6-96	2-17-96	
1. PR	3	3	3	1	
2 GM	3	3	3	1	
3 MR	3	3	3	1	
4 AN	3	3	3	1	
5 KS	3	3	3	1	
6 QT	3	3	3	1	
7 MC	3	3	3	1	
8 DC	3	3	3	1	
9 AN	3	3	3	1	
10 TD	3	3	3	1	
11 DT	3	3	3	1	
12 GH	3	3	3	1	
PR	3	3	3	1	
14 QR	3	3	3	1	
15 VT	3	3	3	1	
16 QD	3	3	3	1	
17 AV	3	3	3	1	
18 TD	3	3	3	1	
19 QT	3	3	3	1	
20 QT	3	3	3	1	
21 RR	3	3	3	1	
22 SL	3	3	3	1	
23 MP	3	3	3	1	
24 MM	3	3	3	1	
25 AR	3	3	3	1	

Technician

Investigator

2/17/96
Date

HRR

Project 6907

IRRITATION - SENSITIZATION STUDY

SCORING SCALE

0 = No Reaction
± = Questionable Erythema
+1 = Definite Erythema
+2 = Erythema & Edema
+3 = Erythema, Edema & Vesiculation
+4 = Erythema, Edema, Vesiculation, Hemorrhage & Bulla Formation

O B S E R V A T I O N S

A = 7 a.m. B = 1 p.m. C = 7 p.m.

DATES	1-25-96			1-26-96			1-27-96			1-28-96			1-29-96		
SUB. I.D.	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
1-PR		0	0	0	0	0	0	0	0	0	0	0	0	0	0
2-GM		+1	+1	+1	+1	±	±	±	±	+±	±	±	±	±	±
3-MR		0	0	0	0	0	0	0	0	0	0	0	0	0	0
4-AN		0	0	0	0	0	0	0	0	0	0	0	0	0	0
5-KS		0	0	0	±	0	0	0	0	0	0	0	0	0	0
6-JT		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7-MM		0	0	0	±	0	0	0	0	0	0	0	0	0	0
8-DC		0	0	0	+1	0	0	0	0	0	0	0	0	0	0
9-DN		0	0	0	0	0	0	0	0	0	0	0	0	0	0
10-TD		0	0	0	0	0	0	0	0	0	0	0	0	0	0
11-DT		0	0	±	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1
12-CH		0	0	0	±	0	0	0	0	0	0	0	0	0	0
13-FB		0	0	0	0	0	0	0	0	0	0	0	0	0	0
14-DE		0	0	0	0	0	0	0	0	0	0	0	0	0	0
15-NT		0	0	0	0	0	0	0	0	0	0	0	0	0	0
16-CD		0	0	0	±	0	0	0	0	0	0	0	0	0	0
17-AV		0	0	0	0	0	0	0	0	0	0	0	0	0	0
18-TD		0	0	0	0	0	0	0	0	0	0	0	0	0	0
19-JT		0	0	0	0	0	0	0	0	0	0	0	0	0	0
20-CT		0	0	0	0	0	0	0	0	0	0	0	0	0	0
21-RR		0	0	0	0	0	0	0	0	0	0	0	0	0	0
22-SL		0	0	0	0	0	0	0	0	0	0	0	0	0	0
23-MP		0	0	0	0	0	0	0	0	0	0	0	0	0	0
24-MM		0	0	0	0	0	0	0	0	0	0	0	0	0	0
25-DJR		0	0	0	0	0	0	0	0	0	0	0	0	0	0

Technician

Investigator

Date 2/7/96

HAPR

Project 6907

IRRITATION - SENSITIZATION STUDY

SCORING SCALE

0 = No Reaction
± = Questionable Erythema
+1 = Definite Erythema
+2 = Erythema & Edema
+3 = Erythema, Edema & Vesiculation
+4 = Erythema, Edema, Vesiculation, Hemorrhage & Bulla Formation

O B S E R V A T I O N S

A = 7 a.m. B = 1 p.m. C = 7 p.m.

DATES	1-30-96			1-31-96			2-1-96			2-2-96			2-3-96		
SUB. I.D.	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
1-PR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2. GH	±	±	±	±	0	0	0	0	0	0	0	0	0	0	0
3 MR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4-AN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5-RS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6-QT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7-MM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8-DC	+1	±	±	±	0	0	0	0	0	0	0	0	0	0	0
9-QN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10-TD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11-DT	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1
12 GH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13 PRG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14-QR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15 NT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16 QD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17 AV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18 TD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19 QT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20 GT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21 PR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22 SL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23 MP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24 MM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25 PJC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Technician

Investigator

Date 4/7/96

HAPR

Project 6907

IRRITATION - SENSITIZATION STUDY

SCORING SCALE

0 = No Reaction
± = Questionable Erythema
+1 = Definite Erythema
+2 = Erythema & Edema
+3 = Erythema, Edema & Vesiculation
+4 = Erythema, Edema, Vesiculation, Hemorrhage & Bulla Formation

O B S E R V A T I O N S

A = 7 a.m. B = 1 p.m. C = 7 p.m.

DATES	2-4-96			2-5-96			2-6-96			2-7-96					
SUB. I.D.	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
1-PR	0	0	0	0	0	0	0	0	0	0	0	0			
2-GH	0	0	0	0	0	0	0	0	0	0	0	0			
3-MR	0	0	0	0	0	0	0	0	0	0	0	0			
4-AN	0	0	0	0	0	0	0	0	0	0	0	0			
5-RS	0	0	0	0	0	0	0	0	0	0	0	0			
6-JT	0	0	0	0	0	0	0	0	0	0	0	0			
7-MC	0	0	0	0	0	0	0	0	0	0	0	0			
8-DC	0	0	0	0	0	0	±	±	±	0	0	0			
9-JN	0	0	0	0	0	0	0	0	0	0	0	0			
10-TD	0	0	0	0	0	0	0	0	0	0	0	0			
11-DT	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1	+1			
12-GH	0	0	0	0	0	0	0	0	0	0	0	0			
13-JR	0	0	0	0	0	0	0	0	0	0	0	0			
14-JR	0	0	0	0	0	0	0	0	0	0	0	0			
15-JT	0	0	0	0	0	0	0	0	0	0	0	0			
16-JD	0	0	0	0	0	0	0	0	0	0	0	0			
17-AV	0	0	0	0	0	0	0	0	0	0	0	0			
18-TD	0	0	0	0	0	0	0	0	0	0	0	0			
19-JT	0	0	0	0	0	0	0	0	0	0	0	0			
20-BT	0	0	0	0	0	0	0	0	0	0	0	0			
21-RL	0	0	0	0	0	0	0	0	0	0	0	0			
22-SL	0	0	0	0	0	0	0	0	0	0	0	0			
23-PP	0	0	0	0	0	0	0	0	0	0	0	0			
24-MM	0	0	0	0	0	0	0	0	0	0	0	0			
25-JR	0	0	0	0	0	0	0	0	0	0	0	0			

Technician

Investigator

2/7/96
Date

KHR

Project 6907

RRITATION - SENSITIZATIC STUDY

SCORING SCALE

0 = No Reaction
± = Questionable Erythema
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O B S E R V A T I O N S

A = 7 a.m. B = 1 p.m. C = 7 p.m.

DATES	2-18-96			2-19-96											
SUB. I. D	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
1-PR	0			0											
2-PH	0			0											
3-MR	0			0											
4-AN	0			0											
5-RS	0			0											
6-CT	0			0											
7-MC	0			0											
8-DC	0			0											
9-CN	0			0											
10-AD	0			0											
11-DT	0			0											
12-SH	0			0											
13-PM	0			0											
14-JC	0			0											
15-MT	0			0											
16-DD	0			0											
17-JV	0			0											
18-AD	0			0											
19-QT	0			0											
20-BT	0			0											
21 LR	0			0											
22 KJ	0			0											
23 MP	0			0											
24 MM	0			0											
25-JF	0			0											

Technician

Investigator

Date 2/19/96